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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/591,632	06/09/2000	Susan Lindquist	27373/34978A	2820
7590 10/14/2008				
Marshall O'Toole Gerstein Murray & Borun 6300 Sears Tower 233 South Wacker Drive Chicago, IL 60606-6402			EXAMINER CHERNYSHEV, OLGA N	
			ART UNIT 1649	PAPER NUMBER
			MAIL DATE 10/14/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

09/591,632

## Applicant(s)

LINDQUIST ET AL.

## Examiner

Olga N. Chernyshev

## Art Unit

1649

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 67, 81, 101, 103-110, 117, 118, 123-129, 132-135, 137-140 and 144-163 is/are pending in the application.
- 4a) Of the above claim(s) 67, 81, 101, 103-110, 117, 118, 146-149, 156 and 162 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 124, 127, 132-135, 137 and 138 is/are allowed.
- 6) ☒ Claim(s) 123, 125, 126, 128, 129, 139, 140, 144, 145, 150-155, 157-161 and 163 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Response to Amendment***

1. Claims 123-125, 127, 128, 144, 145, 150 and 156-162 have been amended, claims 121, 122, 130, 131 and 143 have been cancelled and claim 163 has been added as requested in the amendment filed on September 10, 2008. Following the amendment, claims 67, 81, 101, 103-110, 117, 118, 123-129, 132-135, 137-140, 144-163 are pending in the instant application.

2. Claims 67, 81, 101, 103-110, 117, 118, 146-149, 156 and 162 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Papers filed on May 13, 2002 and May 09, 2005.

3. Claims 123-129, 132-135, 137-140, 144, 145, 150-155, 157-161 and 163 are under examination in the instant office action.

4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

5. Applicant's arguments filed on September 10, 2008 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

***Claim Rejections - 35 USC § 112***

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 123, 125, 126, 128, 129, 139-140, 144, 145, 150-155 and 157-161 and 163, as currently presented, are rejected under 35 U.S.C. 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

8. Claims 125 and 128 stand vague and indefinite for reciting limitation “exactly one amino acid” for reasons of record in section 11 of paper mailed on January 16, 2008. Applicant traverses the rejection by arguing that the base claim encompasses “purified polypeptide comprising a SCHAG amino acid sequence that is at least 90% identical to amino acids 2 to 253 of SEQ ID NO: 2 (emphasis added). The claimed polypeptides are therefore not limited to one substitution of one amino acid within SEQ ID NO: 2 since 90% identity as recited in the claims would encompass polypeptides having more than a single substitution”. Applicant’s argument has been fully considered but is not persuasive because while the base claims recite polypeptides with more than one substitution (90% identity), only one amino acid has been specifically and always replaced with either cysteine, lysine, glutamate, aspartate or arginine at position 2 or 184, respectively.

9. Claims 126 and 129 are vague and ambiguous for recitation “wherein the amino acid with a reactable side chain is a cysteine or a glutamate residue”. It appears that claims are intended to limit the claimed subject matter to polypeptides with substitutions for specific amino acids; however, the presence of limitation “residue” encompasses position of the amino acid within the sequence. Deletion of the limitation “residue” would obviate this ground of rejection.

10. Claims 144 and 145 are indefinite for recitation “wherein the sequence self-coalesces”. Applicant is advised that “sequence” is a term, which describes the structure of the molecule and, therefore cannot coalesce, aggregate, form fibrils etc. Amendment to the claims to recite “wherein the polypeptide self-coalesces” would obviate this ground of rejection.

11. Claim 150 is vague and ambiguous for recitation of a polypeptide with "at least one substituent attached to a side chain [...]" wherein the side chain is one that is exposed to the environment". Claim 150, as currently amended, does not require any substitutions at any positions for amino acids with reactive chains, and encompasses the polypeptide of SEQ ID NO: 2 conjugated to another peptide, labeled etc. Therefore, the significance of limitation "side chain exposed to the environment" is not obvious.

12. Claims 152-154, 159-161 and 163 are indefinite for recitation of attachments of substitutions to different amino acids within the SEQ ID NO: 2 recited in claim 150, and the structure of the claimed molecular embodiments is not clear. For example, claim 154 is directed to a polypeptide with a substitution at position 2, while the claim depends from claim 150 limited to the polypeptide of SEQ ID NO: 2 with no substitutions at any positions. Therefore, claims 152-154, 159-161 and 163 are indefinite or improperly dependent claims.

13. Claim 158 recites the limitation "two different substituents" in claim 150. There is insufficient antecedent basis for this limitation in the claim.

14. Claims 123, 139, 140, 151, 155 and 157 are indefinite for being dependent from indefinite claims.

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 150, 151, 155 and 157, as currently amended, are rejected under 35 U.S.C. 103(a) as being unpatentable over Kushnirov et al., 1988 (Gene, 66, pp. 45-54).

Claims 150, 151, 155 and 157, as presented are drawn to polypeptides comprising fragments 2-113 or 2-253 of SEQ ID NO: 2, with no amino acid substitutions, which are labeled or fused with other different proteins, or attached to a solid support by using well-known techniques in the art of protein modification. Thus, the claimed subject matter encompasses Sup35 polypeptide, first described by Kushnirov et al. in 1988, modified to add certain substituents. For reasons of record fully explained in the previous office actions, the Examiner maintains that modification of a known protein using known techniques renders the instant invention obvious.

#### ***Allowable Subject Matter***

17. Claims 124, 127, 132-135 and 137-138 are allowed as directed to polypeptides with substitutions at positions 2 and 184 of SEQ ID NO: 2. Applicant is advised that withdrawn claims directed to fibers comprising the allowed polypeptides could be rejoined as encompassing allowable subject matter as well.

#### ***Conclusion***

18. Claims 124, 127, 132-135 and 137-138 are allowed. Claims 123, 125, 126, 128, 129, 139-140, 144, 145, 150-155 and 157-161 and 163 are rejected.

19. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Olga N. Chernyshev, Ph.D./  
Primary Examiner, Art Unit 1649